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10/664,817	09/17/2003	Barry Reisberg	1049-1-034N	3446

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EXAMINER	
ROYDS, LESLIE A	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 05/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/664,817	REISBERG, BARRY	
	Examiner	Art Unit	
	Leslie A. Royds	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 November 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-66* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-66* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-66 are presented for examination.

Applicant's "Response to Restriction/Election Requirement" filed November 26, 2004 following the Office Action dated October 26, 2004, electing Group I (claims 23-35 and 56-66), drawn to a method of treating age associated memory impairment (AAMI), mild cognitive impairment (MCI), Alzheimer's Disease (AD) or cerebrovascular dementia (CVD) by administering (i) at least one first agent capable of inhibiting neuronal cell cycle progression and (ii) at least one second agent capable of reducing mitogenic stimulation, is acknowledged. Such an election corresponds to a method of treating AAMI, MCI, AD or CVD where the at least one first agent is selected from the group of compounds listed in claim 4, for example, and where the at least one second agent is an anti-inflammatory agent selected from the group of compounds listed in claims 30-34, for example. The restriction requirement has been modified to also include those claims directed to the use of one agent (i.e., the at least one first agent) alone. Therefore, the claim set corresponding to this election wherein only at least one of the first agents is required to be administered **or** wherein both the at least one first agent and the at least one second agent are required to be administered for the therapeutic objective of treating AAMI, MCI, AD or CVD is 1-6, 22-27, 29-39, 55-60 and 62-66 and such is the claim set to be examined on the merits.

Further Election/Restriction Requirement

Further restriction of the present claims to one of the following inventions is required under 35 U.S.C. 121.

A. Applicant is required to elect one of the following groups corresponding to the **at least one first agent**:

I. Claims 1, 23, 36 and 56, wherein the at least one first agent is minocycline or any tetracycline family derivative capable of crossing the blood brain barrier, classified in class 514, subclass 152, for example.

II. Claims 1, 23, 36 and 56, wherein the at least one first agent is acetylsalicylic acid or any salicylate which inhibits early phase cell cycle progression, classified in class 514, subclass 165, for example.

III. Claims 1, 23, 36 and 56, wherein the at least one first agent is sirolimus or any sirolimus derivative capable of inhibiting early cell cycle progression, classified in class 514, subclass 326, for example.

IV. Claims 1, 23, 36 and 56, wherein the at least one first agent is flavopiridol, classified in class 514, subclass 327, for example.

V. Claims 1, 23, 36 and 56, wherein the at least one first agent is ciclopirox, classified in class 514, subclass 345, for example.

VI. Claims 1, 23, 36 and 56, wherein the at least one first agent is a paulone, classified in class 514, various subclasses, depending on the structure, for example.

VII. Claims 1, 23, 36 and 56, wherein the at least one first agent is indirubin, classified in class 514, subclass 418, for example.

VIII. Claims 1, 23, 36 and 56, wherein the at least one first agent is fascaplycin, classified in class 514, subclass 280, for example.

IX. Claims 1, 23, 36 and 56, wherein the at least one first agent is olomoucine, classified in class 514, subclass 263.4, for example.

X. Claims 1, 23, 36 and 56, wherein the at least one first agent is roscovitine, classified in class 514, subclass 263.4, for example.

XI. Claims 1, 23, 36 and 56, wherein the at least one first agent is Aragusterol A, classified in class 514, subclass 172, for example.

XII. Claims 1, 23, 36 and 56, wherein the at least one first agent is valproate, classified in class 514, subclass 557, for example.

XIII. Claims 1, 23, 36 and 56, wherein the at least one first agent is N-(3-chloro-7-indolyl)-1,4-benzenedisulfamide, classified in class 514, subclass 415, for example.

XIV. Claims 1, 23, 36 and 56, wherein the at least one first agent is the farnesyl transferase inhibitor R115777, classified in class 514, subclass 312, for example.

XV. Claims 1, 23, 36 and 56, wherein the at least one first agent is the farnesyl transferase inhibitor SCH66336, classified in class 514, subclass 296, for example.

XVI. Claims 1, 23, 36 and 56, wherein the at least one first agent is the farnesyl transferase inhibitor BMS-214662, classified in class 514, subclass 221, for example.

XVII. Claims 1, 23, 36 and 56, wherein the at least one first agent is sodium butyrate, classified in class 514, subclass 557, for example.

B. Applicant is required to elect one of the following groups corresponding to the **at least one second agent (i.e., an anti-inflammatory agent)**:

XVIII. Claims 23, 36 and 56, wherein the at least one second agent is an NSAID selected from the group consisting of ibuprofen, naproxen, celecoxib, rofecoxib, sulindac, piroxicam, indomethacin, etodolac, nabumetone, tolmetin, diclofenac, ketoprofen, apazone and meloxicam, classified in class 514, subclasses 226.5, 406, 420 or 570, for example, depending on the agent used.

XIX. Claims 23, 36 and 56, wherein the at least one second agent is prednisone, classified in class 514, subclass 179, for example.

XX. Claims 23, 36 and 56, wherein the at least one second agent is cyclosporine A, classified in class 514, subclass 11, for example.

XXI. Claims 23, 36 and 56, wherein the at least one second agent is tacrolimus, classified in class 514, subclass 326, for example.

Applicant must choose one group from Section A (i.e., the at least one first agent) and one group from Section B (i.e., the at least one second agent) in order to fully comply with the present requirement.

Claims 1-6, 22-27, 29-39, 55-60 and 62-66 link Inventions I through XVII and claims 22-27, 29-39, 55-60 and 62-66 link Inventions XVIII through XXI. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 1-6, 22-27, 29-39, 55-60 and 62-66. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to

examination in the instant application. Applicant is advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP §804.01.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, separate classifications, and also that the search required for any one of the above groups does not necessarily result in a comprehensive search of any one or more of the other groups, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the at least one first agent and the at least one second agent to be examined even though the requirement be traversed (37 C.F.R. 1.143).

Should Applicant wish, a traverse may be made on the grounds that the agents of Groups I-XVII and Groups XVIII-XXI are not patentably distinct. If made, Applicant should submit evidence or identify such evidence now of record showing the agents to be obvious variants or clearly admit on the record that this is the case. In either instance, if the Examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the invention.

Applicant's election **with traverse** of Group IV (claims 23-35 and 56-66), drawn to a method of treating age associated memory impairment (AAMI), mild cognitive impairment (MCI), Alzheimer's Disease (AD) or cerebrovascular dementia (CVD) by administering (i) at least one first agent capable of inhibiting neuronal cell cycle progression and (ii) at least one second agent capable of reducing mitogenic stimulation, in the reply filed November 26, 2004, is acknowledged by the Examiner. The traversal is on the grounds that the groups designated by the Examiner in the previous Office Action are not defined as having "properties so distinct as to warrant separate Examination and Search" (see Applicant's remarks at page 3, paragraph 3) and that "a search for any of the methods separately classified by the Examiner as the invention of elected Group IV would require an additional search of the **identical** classes wherein the claims of Group III are classified, thus resulting in a duplicate search for the same material" (see Applicant's remarks at page 4, paragraph 1).

Applicant's traverse has been carefully considered, but is not found to be persuasive. Although Applicant has acknowledged that each agent is capable of a common function, such as, for example, that the at least one first agent is capable of inhibiting neuronal cell cycle progression (see claim 1 or 23, for example), such agents do not share a common structural element as evidenced by their chemical structures and their separate classification status in the art. Furthermore, the Examiner has noted that the art does not necessarily recognize the agents listed as Groups I through XVII as sharing the common structural and common utility features as asserted by Applicant. For the reasons set forth above, the at least one first agent recited in the present claims is considered to be one of 17 independent and patentably distinct groupings and the at least one second agent is considered to be one of four independent and patentably distinct

groupings. Each group of agents recited above is differently search, such that a complete and comprehensive search of the prior art for any one of the groups of agents based on evidence of distinct and different structural and functional features as set forth above. Therefore, the groups of agents recited in the present claims are considered patentably distinct and/or independent, absent factual evidence to the contrary, and a search for all 17 groups of at least one first agent and all four groups of at least one second agent recited above would constitute an undue burden on the Examiner. Considering the shear number of agents used for the therapeutic objective of treating AAMI, MCI, AD or CVD, there would exist, at minimum, 68 possible combinations of agents to be employed in this method of treatment. Such is further evidence that an undue burden would be placed on the Examiner in considering all of the combinations of agents recited in the present claims. Furthermore, execution of a search encompassing all of Applicant's multiple combinations of agents, and thus, separate and distinct inventions, would not only constitute an undue burden on the Examiner, but *consideration of the findings* of such a search in accordance with the requirements of the law under 35 U.S.C. §§ 101, 102, 103 and 112 would be unduly onerous.

A telephone call was not made to the Office of Klauber & Jackson to request an oral election due to the complex nature of the present restriction/election requirement. Such is in accordance with MPEP §812.01, which states "However, no telephone communication need be made where the requirement for restriction is complex, the application is being prosecuted by the Applicant *pro se*, or the Examiner knows from past experience that an election will not be made by telephone."

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The Examiner can normally be reached on Monday-Friday (8:30 AM-6:00 PM), alternate Fridays off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Christopher Low can be reached on (571)-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-272-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Leslie A. Royds
Patent Examiner
Art Unit 1614

May 10, 2005

RAYMOND HENLEY III
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